

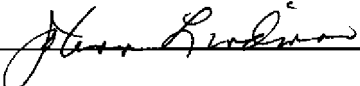
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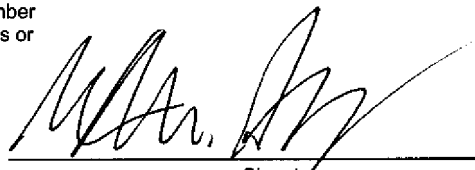
PTO/SB/33 (08-08)

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PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
I hereby certify that this correspondence is being electronically transmitted to the USPTO addressed to "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450		Application Number	Filed
on <u>December 21, 2010</u>		10/648,459	August 26, 2003
Signature <u></u>		First Named Inventor	
Typed or printed name <u>JoAnn Lindman</u>		Thomas Yung-Hui Chien	
		Art Unit	Examiner
		3731	Houston, Elizabeth
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p> <p>Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers, if appropriate. Please charge any additional fees or credit overpayment to Deposit Account No. 50-0413.</p> <p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. <u>36,926</u> Registration number</p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p> <p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p> <p><input type="checkbox"/> *Total of _____ forms are submitted.</p>			


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Telephone number
Dec. 21, 2010
Date

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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In response to the Final Office Action of July 12, 2010 and the Advisory Action of October 1, 2010, Applicants hereby request a Pre-Appeal Conference and file this Pre-Appeal Conference Brief concurrently with a Notice of Appeal. Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a *prima facie* rejection.

Claims 1, 4-7, 9, 10, 14-16, 18, 19, and 23-26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lashinski (U.S. Patent No. 6,579,305) in view of Lau et al. (U.S. Patent No. 5,421,955) and further in view of Stack et al. (U.S. Patent No. 6,264,683). After careful review, Applicants must respectfully traverse this rejection.

With respect to independent claims 1, 14, and 23, the Final Office Action acknowledges that Lashinski does not disclose or suggest all of the structural limitations of the claims. Lau et al. and Stack et al. are introduced as providing or suggesting the missing limitations. Applicants submit that the asserted combination of references appears to be improper.

With respect to Lau et al., Applicants note that Lashinski expressly discloses that controlled leakage of the temperature-controlled fluid from the balloon maintains the temperature of the fluid in the balloon (column 4, lines 55-60), and also Lashinski expressly states that “[t]he fluid is continually replenished through inflation lumen 25, thus maintaining the pressure and temperature of the fluid in balloon 27” (see column 5, lines 43-47). The closed system of Lau et al., which the Examiner has proposed to use to “simplify” the device of Lashinski, does not appear to permit the required replenishment. Without the replenishment disclosed by Lashinski, it appears that the fluid inside the balloon, which directly affects the expansion of the surrounding stent, would not be maintained at the desired temperature and pressure. As the balloon cools (the elevated temperature of the “warm” fluid in the balloon would naturally and necessarily be reduced by the relatively cooler surrounding environment), fluid would have to be removed under vacuum, thereby reducing the pressure in the balloon, and then replaced with fluid at a higher temperature – effectively cycling the fluid temperature and pressure up and down rather than maintaining the temperature and pressure. Alternatively, additional fluid having an elevated temperature will need to be added to the fluid already in the balloon, thereby increasing the pressure within the balloon, and not maintaining the pressure as required by Lashinski. Neither method appears to meet the requirements of the original system.

In the Advisory Action, the Examiner states “release of the heated fluid at the distal end

of the stent is not essential to the function of the device, as is asserted by applicant". Applicants respectfully deny making such an assertion. Instead, Applicants argued that replacing the flow-through system of Lashinski with the closed system of Lau et al. would change the means of maintaining the temperature and/or pressure (as required by Lashinski), impermissibly altering the principle of operation of Lashinski. Furthermore, regardless of where the fluid is released, Lashinski discloses releasing the fluid as a necessary part of the function of maintaining a constant temperature and/or pressure. The system produced when Lashinski is modified by Lau et al. does not permit the temperature and/or pressure to be maintained by releasing fluid.

Therefore, modification of Lashinski in view of Lau et al. appears to impermissibly alter the principle of operation of Lashinski by removing the continuous replenishment of warm fluid which maintains the temperature and pressure within the balloon using a flow-through system, rendering it unsuitable for its intended use (see MPEP 2143.01 V-VI). As such, the proposed modification in view of Lau et al. appears to be improper.

With respect to Stack et al. and in contrast to the assertions of the Examiner, Stack et al. do not appear to disclose a stent delivery device with an inner tube having a distal tip with a proximal edge diameter and an outer tube defining a distal end diameter. Instead, Stack et al. appear to disclose a single catheter 10 comprising shaft 12 having two side-by-side lumens, inflation lumen 15 which extends to a proximal end of a balloon, and guidewire lumen 16 which extends through the balloon. However, one of ordinary skill in the art would not consider the side-by-side construction of Stack et al. as comprising inner and outer tubes, the inner tube being disposed within the outer tube, as required by the claims. Furthermore, Stack et al. do not appear to disclose two tubes arranged concentrically or otherwise so as to form an annular space between them, as required by the claims. Accordingly, one of ordinary skill in the art would not look to Stack et al. to modify the device disclosed by Lashinski.

Separately, Applicants note that distal stent bumper 20 of Stack et al. appears to have an exaggerated protrusion to one side of inflation lumen 16, so as to provide concentric mounting of the balloon and stent with respect to a central axis of shaft 12. The addition of stent bumper 20 to the generally concentric tubes of Lashinski, as proposed by the Examiner, would appear to create an undesirable protrusion to one side of the device, which may create interference or otherwise negatively affect the insertion or withdrawal of the device through narrowed vessels within the vasculature. Applicants submit that one of ordinary skill in the art would not modify

Lashinski with this feature of Stack et al. when seeking to navigate narrowed vessels.

In the Advisory Action, the Examiner treated these two separate arguments against the combination with Stack et al. as a single argument, and argued that “the test for obviousness is not whether the features of a secondary reference can be bodily incorporated into the structure of the primary reference...” Applicants did not argue that the stent bumper feature of Stack et al. cannot be bodily incorporated into Lashinski, and such a remark appears to be an attempt to avoid responding to the arguments actually presented. First, Applicants noted that Stack et al. do not disclose the structure which the Examiner asserts is disclosed and purportedly leads one of ordinary skill in the art to consider Stack et al. when modifying Lashinski. Secondly, one of ordinary skill in the art would not make the proposed modification because the modification would produce undesirable results in view of the primary reference device’s disclosed use.

For at least these reasons, Lashinski, Lau et al., and Stack et al., alone or in combination, do not appear to properly disclose or suggest all of the elements of independent claims 1, 14, and 23, as is required to establish a *prima facie* rejection. Accordingly, independent claims 1, 14, and 23 are believed to be patentable over the cited references. Since claims 4-7, 9, 10, 15, 16, 18, 19, and 24-26 depend from independent claims 1, 14, and 23 and add additional elements thereto, these claims are also believed to be patentable over the cited references.

Additionally, Applicants respectfully point out that none of the cited references appear to disclose or suggest the inner tube comprises a distal radiopaque marker disposed immediately proximal to the distal tip and a proximal radiopaque marker immediately distal to the distal end of the outer tube, as required by dependent claim 10, in addition to the deficiencies noted above with respect to claim 1. Since the cited references, alone or in combination, do not disclose all of the elements of the claim, the rejection of claim 10 appears to be improper. Applicants respectfully request that the rejection be withdrawn.

Claim 8 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lashinski in view of Lau et al. and Stack et al. as applied to claim 1, and further in view of Klein (U.S. Patent No. 6,605,107). Claim 17 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lashinski in view of Lau et al. and Stack et al. as applied to claim 16, and further in view of Rabkin et al. (U.S. Patent No. 6,676,692). Claim 21 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lashinski in view of Lau et al. and Stack et al. as applied to claim 19, and further in view of Healey et al. (U.S. Patent No. 6,607,553). After careful review,

Applicants must respectfully traverse these rejections. As discussed above, independent claims 1 and 14 are believed to be patentable over Lashinski in view of Lau et al. and Stack et al. Klein, Rabkin et al., and Healey et al. do not appear to remedy the shortcomings of Lashinski, Lau et al., and Stack et al. with respect to claims 1 and 14. Accordingly, claims 1 and 14 are believed to be patentable over the cited combinations. Since claims 8, 17, and 21 depend therefrom and add additional elements thereto, these claims are also believed to be patentable over the cited references. Withdrawal of the rejections is respectfully requested.

Claims 3, 12, 13, 20, and 27-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Lashinski in view of Lau et al. and Stack et al. as applied to claims 1 and 14, and further in view of Kasprzyk et al. (U.S. Patent No. 5,035,694). After careful review, Applicants must respectfully traverse this rejection. As discussed above, independent claims 1 and 14 are believed to be patentable over Lashinski, Lau et al., and Stack et al. Independent claim 27 contains similar elements and is subject to the same arguments. Kasprzyk et al. do not appear to remedy the shortcomings of Lashinski, Lau et al., and Stack et al. with respect to claims 1, 14, and 27. Therefore, claims 1, 14, and 27 are believed to be patentable over the cited combination. Since claims 3, 12, 13, 20, 28, and 29 depend therefrom and add additional elements thereto, these claims are also believed to be patentable over the cited references.

Additionally, the Examiner asserts that Kasprzyk et al. disclose “a coil heating element (50, 51) for supplying heat to the immediate area surrounding a balloon” (Final Office Action, page 7). Applicants respectfully disagree. As stated previously, elements 50 and 51 are not disclosed as “supplying heat” to any portion of the device of Kasprzyk et al. Instead, Kasprzyk et al. expressly disclose that elements 50 and 51 direct electrical power from a source exterior to the catheter to the electrically conductive layer 52 on an inside surface of the balloon, where the electrically conductive layer 52 provides heating (and would thus be considered a heating element by one of ordinary skill in the art). Applicants note that electrically conductive layer 52 is not a coil, as required by dependent claim 2, and electrically conductive layer 52 is not “positioned on the distal end of the inner tube” as required by independent claim 27.

In the Advisory Action, the Examiner states “[i]t is unclear how applicant can claim that element 50 and 51 do not supply heat to any portion of the device when they are clearly supplying heat to a layer of the balloon.” Applicants find the above statement to be fundamentally flawed and in direct contradiction of the express teachings of the cited reference.

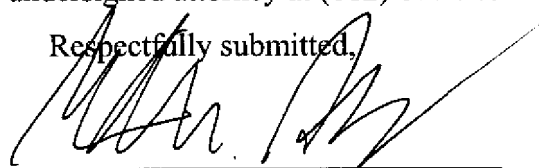
As noted above, Kasprzyk et al., at column 5, line 66 to column 6, line, expressly disclose “electrical conductors 50 and 51 for directing electrical power from a source (not shown) exterior to the catheter to the electrically conductive later 52 provided on the interior of the balloon”. Elements 50 and 51 do not supply heat to a layer of the balloon, as asserted by the Examiner. They supply electrical power to that layer, and the layer produces heat from that electrical power (column 6, lines 16-19). Applicants submit that it is improper for the Examiner to interpret the purpose and function of the structure of the cited reference in a way that directly conflicts with the express teachings of that reference. For at least these reasons, the rejection in view of Kasprzyk et al. appears to be improper and withdrawal of the rejection is respectfully requested.

Claim 30 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lashinski in view of Lau et al. and Stack et al. and Kasprzyk et al. as applied to claim 27, and further in view of Rabkin et al. Claim 31 was rejected under 35 U.S.C. §103(a) as being unpatentable over Lashinski in view of Lau et al. and Stack et al. and Kasprzyk et al. as applied to claim 27, and further in view of Healey et al. After careful review, Applicants must respectfully traverse this rejection. As discussed above, independent claim 27 is believed to be patentable over Lashinski in view of Lau et al., Stack et al., and Kasprzyk et al. Neither Rabkin et al. nor Healey et al. appear to remedy the shortcomings of Lashinski, Lau et al., Stack et al., and Kasprzyk et al. with respect to claim 27. Accordingly, claim 27 is believed to be patentable over the cited combinations. Since claims 30 and 31 depend therefrom and add additional elements thereto, these claims are also believed to be patentable over the cited references. Withdrawal of the rejections is respectfully requested.

In view of the foregoing, all pending claims are believed to be in a condition for allowance. Withdrawal of the rejections is respectfully requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Date: Dec. 21, 2010

Respectfully submitted,



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